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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/671,995	09/29/00	CHARI	R 104322.198 U

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HALE & DORR LLP
THE WILLARD OFFICE BUILDING
1455 PENNSYLVANIA AVE, NW
WASHINGTON DC 20004

HM12/1009

EXAMINER	
RAWLINGS,S	
ART UNIT	**PAPER NUMBER**
1642	11

DATE MAILED: 10/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/671,995	Applicant(s) CHARI, RAVI V. J.	
	Examiner Stephen L. Rawlings, Ph.D.	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32,40,41 and 44-89* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32,40,41 and 44-89* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Election facsimile sheet* .

DETAILED ACTION

1. The election filed on June 26, 2001 in Paper No. 10 is acknowledged and has been entered.

2. Claims 1-32, 40, 41, and 44-89 are pending in the application and are currently subject to restriction.

Election/Restrictions

3. Applicant's request in Paper No. 10 for reconsideration of the restriction requirement made in the previous Office Action (Paper No. 8) is acknowledged. Upon consideration of the record in view of Applicants' remarks, the restriction requirement made in the previous Office Action is withdrawn and a new restriction requirement is set forth below.

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group 1. Claims 1-32, drawn to a method for treating cancer, classified in class 424, subclass 178.1 and class 514, subclass 1.

Group 2. Claims 40, 41, and 44-89, drawn to a composition and a kit, classified in class 424, subclass 178.1 and 514, subclass 1.

5. The inventions are distinct, each from the other because of the following reasons:

The inventions in Groups 1 and 2 are not at all related because the products of Group 2 are not specifically used in any of the steps of the claimed methods in Group 1.

If the inventions of Group 1 and 2 were related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product, namely methotrexate.

6. Because these inventions are distinct for the reasons given above and the search required for examination of one group is not co-extensive with the search required for examination of the other, restriction for examination purposes as indicated is proper.

7. This application contains claims directed to patentably distinct species of the claimed invention.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Currently, claims 1, 8, 10, 16, 19, 21, 23, 25, 40, 41, 46, 48, 54, 57, 59, 61, 63, 68, 70, 76, 79, 81, and 85 are generic.

Claim 1 is drawn to patentably distinct species of the invention, wherein the cancer is a cancer of the (a) breast (claim 2), (b) colon (claims 2 and 5), (c) lung (claims 2 and 3), (d) prostate (claim 2), (e) kidney (claim 2), (f) pancreas (claim 2), (g) brain (claim 2), (h) bones (claim 2), (i) ovary (claim 2), (j) testes (claim 2), or (k) a lymphatic organ (claim 2).

Claim 1 is further drawn to patentably distinct species of the invention, wherein the anti-mitotic agent is (a) a maytansinoid (claim 6), (b) a Vinca alkaloid (claim 8), (c) a dolastatin (claim 8), or (d) a cryptophycin (claim 8).

Claim 8 is drawn to patentably distinct species of the invention, wherein the Vinca alkaloid is (a) vincristine, (b) vinblastine, (c) vindesine, or (d) navelbine (claim 9).

Claim 8 is further drawn to patentably distinct species of the invention, wherein the dolastatin is (a) dolastatin 10 or (b) dolastatin 15 (claim 9).

Claim 8 is further drawn to patentably distinct species of the invention, wherein the cryptophycin is (a) cryptophycin 52 or (b) cryptophycin 1 (claim 9).

Claim 10 is drawn to patentably distinct species of the invention, wherein the monoclonal antibody or fragment thereof is (a) humanized N901 or (b) humanized C242 (claim 14).

Claim 1 is further drawn to patentably distinct species of the invention, wherein the chemotherapeutic agent is (a) a taxane (claim 16), (b) a compound that acts through a taxane mechanism (claim 18), (c) a platinum compound (claim 21), (d) a camptothecin compound (claim 25), or (e) a compound that inhibits DNA topoisomerase I (claim 27).

Claim 16 is drawn to patentably distinct species of the invention, wherein the taxane is (a) paclitaxel or (b) docetaxel (claim 17).

Claim 19 is drawn to patentably distinct species of the invention, wherein the epothilone is (a) epothilone A, (b) epothilone B, (c) epothilone C, (d) epothilone D, (e) epothilone E, or (f) epothilone F (claim 20).

Claim 21 is drawn to patentably distinct species of the invention, wherein the platinum compound is (a) cisplatin, (b) carboplatin, (c) oxaliplatin, (d) iproplatin, (e) ormapaltin, or (f) tetraplatin (claim 22).

Claim 23 is drawn to patentably distinct species of the invention, wherein the epipodophyllotoxin is (a) etoposide or (b) teniposide (claim 24).

Claim 25 is drawn to patentably distinct species of the invention, wherein the campotothecin compound is (a) camptothecin, (b) toptecan, (c) irinotecan, or (d) 9-aminocamptothecin (claim 26).

Claim 40 is drawn to patentably distinct species of the invention, wherein the anti-mitotic agent is (a) a maytansinoid (claim 44), (b) a Vinca alkaloid (claim 46), (c) a dolastatin (claim 46), or (d) a cryptophycin (claim 46).

Claim 46 is drawn to patentably distinct species of the invention, wherein the Vinca alkaloid is (a) vincristine, (b) vinblastine, (c) vindesine, or (d) navelbine (claim 47).

Claim 46 is further drawn to patentably distinct species of the invention, wherein the dolastatin is (a) dolastatin 10 or (b) dolastatin 15 (claim 47).

Claim 46 is further drawn to patentably distinct species of the invention, wherein the cryptophycin is (a) cryptophycin 52 or (b) cryptophycin 1 (claim 47).

Claim 48 is drawn to patentably distinct species of the invention, wherein the monoclonal antibody or fragment thereof is (a) humanized N901 or (b) humanized C242 (claim 52).

Claim 40 is further drawn to patentably distinct species of the invention, wherein the chemotherapeutic agent is (a) a taxane compound (claim 54), (b) a compound that acts through a

taxane mechanism (claim 56), (c) a platinum compound (claim 59), (d) a camptothecin compound (claim 63), or (e) a compound that inhibits DNA topoisomerase I (claim 65).

Claim 54 is drawn to patentably distinct species of the invention, wherein the taxane is (a) paclitaxel or (b) docetaxel (claim 55).

Claim 57 is drawn to patentably distinct species of the invention, wherein the epothilone is (a) epothilone A, (b) epothilone B, (c) epothilone C, (d) epothilone D, (e) epothilone E, or (f) epothilone F (claim 58).

Claim 59 is drawn to patentably distinct species of the invention, wherein the platinum compound is (a) cisplatin, (b) carboplatin, (c) oxaliplatin, (d) iproplatin, (e) ormapaltin, or (f) tetraplatin (claim 60).

Claim 61 is drawn to patentably distinct species of the invention, wherein the epipodophyllotoxin is (a) etoposide or (b) teniposide (claim 62).

Claim 63 is drawn to patentably distinct species of the invention, wherein the campotothecin compound is (a) camptothecin, (b) toptecan, (c) irinotecan, or (d) 9-aminocamptothecin (claim 64).

Claim 41 is drawn to patentably distinct species of the invention, wherein the anti-mitotic agent is (a) a maytansinoid (claim 66), (b) a Vinca alkaloid (claim 68), (c) a dolastatin (claim 68), or (d) a cryptophycin (claim 68).

Claim 68 is drawn to patentably distinct species of the invention, wherein the Vinca alkaloid is (a) vincristine, (b) vinblastine, (c) vindesine, or (d) navelbine (claim 69).

Claim 68 is further drawn to patentably distinct species of the invention, wherein the dolastatin is (a) dolastatin 10 or (b) dolastatin 15 (claim 69).

Claim 68 is further drawn to patentably distinct species of the invention, wherein the cryptophycin is (a) cryptophycin 52 or (b) cryptophycin 1 (claim 69).

Claim 70 is drawn to patentably distinct species of the invention, wherein the monoclonal antibody or fragment thereof is (a) humanized N901 or (b) humanized C242 (claim 74).

Claim 41 is further drawn to patentably distinct species of the invention, wherein the chemotherapeutic agent is (a) a taxane compound (claim 76), (b) a compound that acts through a taxane mechanism (claim 78), (c) a platinum compound (claim 81), (d) a camptothecin compound (claim 85), or (e) a compound that inhibits DNA topoisomerase I (claim 87).

Claim 76 is drawn to patentably distinct species of the invention, wherein the taxane is (a) paclitaxel or (b) docetaxel (claim 77).

Claim 79 is drawn to patentably distinct species of the invention, wherein the epothilone is (a) epothilone A, (b) epothilone B, (c) epothilone C, (d) epothilone D, (e) epothilone E, or (f) epothilone F (claim 80).

Claim 81 is drawn to patentably distinct species of the invention, wherein the platinum compound is (a) cisplatin, (b) carboplatin, (c) oxaliplatin, (d) iproplatin, (e) ormapaltin, or (f) tetraplatin (claim 82).

Claim 83 is drawn to patentably distinct species of the invention, wherein the epipodophyllotoxin is (a) etoposide or (b) teniposide (claim 84).

Claim 85 is drawn to patentably distinct species of the invention, wherein the campotothecin compound is (a) camptothecin, (b) toptecan, (c) irinotecan, or (d) 9-aminocamptothecin (claim 86).

8. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

9. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (703) 305-3008. The examiner can normally be reached on Monday-Thursday, alternate Fridays, 8:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C. Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1642

ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

slr
October 3, 2001

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